



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,944	03/22/2001	Keith D. Allen	R-654	8251
26619	7590	12/17/2003	EXAMINER	
DELTA GEN, INC. 740 BAY ROAD REDWOOD CITY, CA 94063			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/815,944	ALLEN ET AL.	
	Examiner	Art Unit	
	Celine X Qian	1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26,28-30,32,33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32 and 33 is/are allowed.
- 6) ☒ Claim(s) 26,28-30 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 26, 28-30, 32, 33 and 35 are pending in the application.

This Office Action is in response to the Amendment filed on 9/22/03.

#### ***Response to Amendment***

Claims 1-25 appear to be cancelled by Applicant. However, the response does not specifically indicate such cancellation. Clarification is required.

The rejection of claims 26, 28, 29 and 35 under 35 U.S.C.103 (a) is maintained for reasons set forth of the record mailed on 6/17/03 and further discussed below.

Claim 30 is rejected under 35 U.S.C. 112 2<sup>nd</sup> paragraph for reasons discussed below.

#### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 28, 29 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansour et al (1988, Nature, vol. 336, No. 24, 348-352), in view of Mountjoy et al. (1992, Science vol. 257, 1248-1251) and Adachi et al (1999, J. Immunology, vol.163: 3363-3368).

In response to the rejection, Applicant argues that the combined teaching of Mansour et al., Mountjoy et al., and Adachi et al does not teach all the limitations recited in the pending claims because none of the references teaches a target construct comprising sequences homologous to specific melanocyte stimulating hormone receptor gene represented by SEQ ID

NO:19, and method of making said construct. Applicant further argues that the amended claims no longer recite intended use of the knockout construct, but the unexpected result of disrupting the melanocyte stimulated hormone receptor gene produced by the claimed targeting construct in mouse. Applicant therefore concludes that the combined references do not teach or suggest all the claim limitations and the claims are not obvious.

Applicant's arguments have been fully considered but they are not persuasive. The teachings of the references are discussed in detailed in the previous office action mailed on 11/19/02 and 6/17/03. The combined teaching of the references gives motivation and reasonable expectation of success to make a MC1-R knockout construct to subsequently generate a knockout mouse study the function of this gene (see detailed discussion in previous office action). Briefly, the Mansour teaches a general method to make knockout construct for homologous recombination in mouse ES cells, and further provides motivation (to study gene function) to make such a construct. Mountjoy provides specific sequences that is required to make a MC1-R knockout construct according to the method taught by Mansour. Adachi further discusses the important role of MSH in inflammatory response which provides additional motivation for studying this MC1-R gene. Contrary to Applicant's assertion, the recitation of "wherein the target construct produces..." is not a limitation of the claim because it does not provide any limitation to the target construct structurally. It would not be considered as unexpected results unless there is evidence that the target construct made according to the combined teaching of the cited references would not produce the disruption in a cell or hypoactivity in a knockout mouse. Consequently, and the combined teaching of the references meets all the claim limitation. Therefore, the obviousness rejection is maintained.

*New Grounds of Rejection*

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: selecting the appropriate ES cells having undergone homologous recombination.

The recitation of “pseudopregnant mouse gives birth” renders the claim indefinite because a pseudopregnant mouse cannot give birth. Amending the claim to recite “said mouse gives birth” would overcome this rejection.

Claims 32 and 33 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Art Unit: 1636

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

*Anne-Marie Falk*

ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER